DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 16 1996

Re: CEDAX® Oral Suspension
Docket No. 96E-0099

#22

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,634,697, filed by Schering-Plough Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CEDAX® Oral Suspension, the human drug product claimed by the patent.

The total length of the regulatory review period for CEDAX® Oral Suspension is 2,641 days. Of this time, 1,179 days occurred during the testing phase and 1,462 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 28, 1988.

   The applicant claims September 29, 1988, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 28, 1988, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: December 20, 1991.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for CEDAX® (NDA 50-686) was initially submitted on December 20, 1991.

3. The date the application was approved: December 20, 1995.

   FDA has verified the applicant's claim that NDA 50-686 was approved on December 20, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Thomas D. Hoffman
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